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CANTOR COLBURN, LLP
55 GRIFFIN ROAD SOUTH
BLOOMFIELD, CT 06002

| EXAMINER | |
|---|---|
| ROZANSKI, MICHAEL T | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/065,960 | AVNIASH ET AL. | |
| | Examiner | Art Unit | |
| | Michael Rozanski | 3768 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-10,13-16,18,20-26,29-35,37 and 39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,13-16,18,20-26,29-35,37 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments with respect to claims 1-10, 13-16, 18, 20-26, 29-35, 37, and 39 have been considered but are moot in view of the new ground(s) of rejection.

Examiner submits that the previous office action was improperly made Final. This Non-Final rejection is based on the reasons given in this response and in the 102 and 103 rejections.

Regarding claims 1, 10, 16, 18, 25, and 37 that cite "gating using the acquired information," it would have been obvious to one with ordinary skill in the art at the time of the invention to utilize the non-electrical sensor to acquire information for cardiac gating and to gate using the acquired information because the SCG waveform contains information for determining intervals between the atrial depolarization and ventricular stimulation pulse events.

With respect to claims 1, 10, and 18 as noted in the office action, the SCG waveform is the mechanical equivalent of the ECG waveform. ECG waveforms are used for determining gating pulse (see para [0004] of Applicant's specification). Therefore, it would have been obvious to utilize the non-electrical sensor to acquired information for cardiac gating because the SCG waveform contains information for determining intervals between the atrial depolarization and ventricular stimulation pulse events. With regard to claim 18, the accelerometer located on the wrist will be responsive to chest vibrations because the source of these vibrations is the same

source that would cause movement on the wrist. Therefore, it would have been obvious to arrange an accelerometer on a wrist as claimed.

With regard to claim 16, it is clarified for the record that measurement based on pressure can be equated with measurement based on force because pressure, by definition, is the exertion of force upon a surface.

With regard to claim 21, interferometers are optical displacement or fiber-optic sensors because such devices are used to measure displacements and are applied to the fiber-optic field (col. 2, lines 2-8). In regard to the argument of force changes being independent of a defined surface area, the Examiner does not find this limitation in the claim. It is noted that the claim stated that the sensor rested "on a vibrating surface", but was amended and taken out in amended claims of 6/29/07. As such, since pressure is the exertion of force on a surface, a proportional output of pressure changes can be equated to proportional output of force changes.

With respect to claims 25 and 37, Scanlon does not disclose utilizing the sensor to acquire information for gating. It would have been obvious to one with ordinary skill in the art at the time of the invention to utilize the non-electrical sensor to acquire information for gating because the output signal based on pressure fluctuation would be useful in determining the time when the best image of an organ is taken.

Newly added claim 39 is addressed below.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by ***Scanlon*** (US 5,853,005).

***Claim 21:*** Scanlon discloses a sound and movement monitor suitable for providing the capability to locally or remotely monitor living organism body functions. A monitoring system 10 is described, which includes a sensor pad 12 defining a fluid-filled chamber 11 and a sensing and monitoring system 13 including an acoustic pressure transducer 14. The transducer 14 is coupled with the chamber and a signal processing and output system 15 for processing output signals from the transducer caused by pressure fluctuations in the pad caused by activity of a living organism in contact with the pad (col. 4, lines 37-54). The system as described is, therefore, capable of being utilized for gating for a medical imaging system. The transducer may be a force, or pressure, transducer that provides an output proportional to pressure changes (col. 2, lines 35-44). Measurement based on pressure can be equated with measurement based on force because pressure, by definition, is the exertion of force upon a surface. Furthermore, it may be a vibratory and/or movement sensor, such as an accelerator, a strain gage, an optical displacement sensor, a fiber-optic sensor, or a chemical, biological, and electrical emission sensor (col. 2, lines 2-8). Interferometers are optical

displacement or fiber-optic sensors because such devices are used to measure displacements and are applied to the fiber-optic field.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 7-10, 13-15, 18, 20, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over ***Schlager et al*** (US 6,024,705).

***Claims 1, 10, and 18:*** Schlager et al. disclose an instrument for a seismocardiographic (SCG) analysis of a patient's cardiac performance. The SCG waveform is the mechanical equivalent of the electrocardiographic (ECG) waveform, and includes point features that correspond to the pumping motion of the heart during systole and diastole. ECG waveforms are used for determining gating pulse (see para [0004] of Applicant's specification). Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention to utilize the non-electrical sensor to acquired information for cardiac gating because the SCG waveform contains information for determining intervals between the atrial depolarization and ventricular stimulation pulse events. This would be useful in determining the time when the best image of an organ is taken.

The sensing transducer 1 may be a suitable accelerometer providing a signal responsive to chest wall vibrations and is secured to the sternum area of a patient's chest 2. The signal from the accelerometer may be used to obtain information for gating, which is described by the applicant as an option for characterizing different attributes of an organ for imaging. Furthermore, an accelerometer is an adaptable device and is fully capable of being arranged on a wrist of a patient to yield information for peripheral pulse gating. Therefore, placing an accelerometer on a patient's wrist would be obvious to one with ordinary skill in the art at the time the invention was made in order to more easily obtain pulse information from a patient (col. 1, lines 10-27; col. 5, lines 35-60).

***Claims 7-9, 14, and 15:*** Schlager et al. disclose a linear prediction coefficient determination function 11 in which the LPA coefficients are calculated for time segments of the SCG waveform, preferably each segment is a heartbeat in length. This permits the SCG analysis instrument provides information regarding the determination of a timing interval between atrial depolarization and ventricular stimulation pulse events prior to displacement of a body part of a patient.

The SCG waveform coefficients are processed in a pattern recognition process unit 12 for classification of the SCG waveform. It is also disclosed that other pattern recognition techniques may be employed including (but not limited to) discriminant analysis, K-Nearest Neighbor classification and classification decision trees. The pattern recognition technique is employed within a computer unit 9 for processing.

Processing includes recording the patient's waveform and would, therefore, provide a training set within the computer database (col. 6, lines 1-29; col. 8, lines 4-11).

While Shlager et al. do not specifically disclose extracting information for gating, it would have been obvious to one with ordinary skill in the art at the time of the invention to utilize the non-electrical sensor to acquired information for cardiac gating because the SCG waveform contains information for determining intervals between the atrial depolarization and ventricular stimulation pulse events. This would be useful in determining the time when the best image of an organ is taken.

***Claims 13 and 39:*** Schlager et al. disclose a linear predication analysis method that includes calculating a first derivative. This mathematical modeling is used to represent a waveform by a number of model coefficients. While Schlager et al. do not specifically disclose a 'jerk' waveform or a 'salient peak,' the mathematical modeling and computer processing is capable of performing the function as claimed and would be obvious to one with ordinary skill in the art at time the invention was made to perform calculations to provide a trigger for cardiac gating (col. 12, lines 35-67; col. 13, lines 1-39). While Shlager et al. do not specifically disclose using the salient-peak as a trigger, it would have been obvious to one with ordinary skill in the art at the time of the invention to utilize the non-electrical sensor to acquired information for cardiac gating because the SCG waveform contains information for determining intervals between the atrial depolarization and ventricular stimulation pulse events, including salient-peak information. This would be useful in determining the time when the best image of an organ is taken.

***Claim 20:*** Schlager et al. disclose an accelerometer and accelerometer output waveform, calculating a time delay for information being transmitted from a heart of the patient to a peripheral pulse, and characterizing the signal. Specifically, phase integrity (lack of phase distortion) is important in a SCG waveform where time intervals contain primary information. Furthermore, there is an autocorrelation function whereby amplitude peak points are selected to determine the heart period and pulse rate. This method has been implemented in comparative testing and the output signal is characterized in a number of ways (col. 8, lines 64-67; col. 10, lines 42-55; Fig. 2a).

6. Claims 16, 24-26, 31, 34, 35, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over ***Scanlon*** (US 5,853,005).

***Claims 16, 24-26, 34, 35, and 37:*** Scanlon discloses a sound and movement monitor suitable for providing the capability to locally or remotely monitor living organism body functions. A monitoring system 10 is described, which includes a sensor pad 12 defining a fluid-filled chamber 11 and a sensing and monitoring system 13 including an acoustic pressure transducer 14. The transducer 14 is coupled with the chamber and a signal processing and output system 15 for processing output signals from the transducer caused by pressure fluctuations in the pad caused by activity of a living organism in contact with the pad (col. 4, lines 37-54). The system as described is, therefore, capable of being utilized for gating for a medical imaging system. The transducer may be a force, or pressure, transducer that provides an output proportional to pressure changes (col. 2, lines 35-44). Measurement based on pressure can be

equated with measurement based on force because pressure, by definition, is the exertion of force upon a surface. Furthermore, it may be a vibratory and/or movement sensor, such as an accelerator, a strain gage, an optical displacement sensor, a fiber-optic sensor, or a chemical, biological, and electrical emission sensor (col. 2, lines 2-8). The system can be used to monitor the peripheral pulse, and may be attached around the wrist, arm, leg, neck, forehead, ankle, torso, or abdomen. The patient-sensor interface may be a fluid-filled, non-metallic, non-conducting tube having a first end and a second end for use in ultrasound systems (col. 13, lines 36-40; col. 14, line 66 – col. 15, line 4).

Scanlon does not disclose utilizing the sensor to acquire information for gating. It would have been obvious to one with ordinary skill in the art at the time of the invention to utilize the non-electrical sensor to acquire information for gating because the output signal based on pressure fluctuation would be useful in determining the time when the best image of an organ is taken.

***Claim 31:*** Scanlon discloses a non-electrical sensor having a bandwidth of at least 125 Hz (Col. 5, lines 20-44).

### *Claim Rejections - 35 USC § 103*

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 2-6, 22, 23, 29, 30, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schlager et al. in view of Scanlon (US Patent No. 5,853,005).

***Claims 2-6:*** Schlager et al. teach all the elements of the current invention, except for imaging systems such as x-ray and ultrasound systems. In the same field of endeavor, Scanlon teaches of a monitoring system capable of being used for gating utilizing an accelerometer, among other non-electrical sensors (col. 15, lines 2-8). Scanlon describes a sensor pad that can be used for gating with MRI, CT scanner, X-ray, and ultrasound systems (col. 15, lines 1-5). It is also taught that chemical, biological, and electrical emission sensors may be employed, which would include a PET-CT imaging system (col. 2, lines 5-8). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the teachings of Scanlon to Schlager et al. in order to facilitate characterization of different attributes of an organ through a variety of imaging techniques.

***Claims 22, 23, 29, and 30:*** Scanlon does not explicitly describe a sensor box, a signal processing function, or a computer analysis station. However, Schlager et al. teach of a sensor 1 being an input to a computer processing instrument 4 via an electrical connection (col. 5, lines 36-52). The signals are transmitted to a data acquisition module, in which signals are converted into digital form. The module is connected to a computer unit 9 that includes a digital signal processing function 10 and additional computer analysis 11 (col. 5, lines 43-61). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the

teachings of Scanlon to Schlager et al. in order to facilitate the transmittal of imaging information.

***Claim 32:*** Schlager et al. disclose all features of claim 1, but do not disclose a method to acquire information for respiratory gating. However, Scanlon teaches of a monitoring system including a pressure transducer that provides output proportional to pressure changes (col. 2, lines 35-41). Although the reference does not explicitly refer to 'respiratory gating,' the system anticipates and is capable of acquiring information for respiratory gating. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made in order to facilitate the monitoring of respiratory functions.

***Claim 33:*** Schlager et al. disclose an accelerometer and accelerometer output signal, integration of the waveform of the autocorrelation function. Furthermore, a filter program is described that may be used for a band pass filter (col. 9, lines 10-64). While Schlager et al. do not specifically disclose a 'salient peak,' subsequent computer processing is described that would allow capability of analyzing the filtered signal for salient peaks and providing a trigger point for gating (col. 10, lines 25-55). However, Schlager et al. do not disclose a process for respiratory gating. In the same field of endeavor, Scanlon teaches that a pressure transducer may be implemented (col. 2, lines 35-44). This respiratory gating characterizes particular points in a variable cycle, as described by the applicant. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to facilitate the monitoring of respiratory functions.

***Conclusion***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Rozanski whose telephone number is 571-272-1648. The examiner can normally be reached on Monday - Friday, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MR

MR

ELENI MANTIS MERCADER
SUPERVISORY PATENT EXAMINER